



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0594; FRL-9958-07]

2,4-D; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of 2,4-D in or on cotton, gin byproducts and amends the existing tolerance on cotton, undelinted seed. Dow AgroSciences requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0594, is available at <http://www.regulations.gov> or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION, CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0594 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA

without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0594, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW. Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 27, 2016 (81 FR 74754) (FRL-9953-98), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8303) by Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.142 be amended by establishing tolerances for residues of the herbicide, 2,4-D (2,4-dichlorophenoxyacetic acid), both free and conjugated, determined as the acid, in or on gin byproducts and undelinted seed of herbicide-tolerant cotton at 1.5 and 0.08 parts per

million (ppm) respectively. That document referenced a summary of the petition prepared by DowAgrosciences, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. Responses to these comments are included in the document titled *Response to Public Comments Received Regarding the Evaluation of Enlist DuoTM on Enlist Corn, Cotton, and Soybeans*, which is available in the docket. This document also includes several comments and responses to those comments that are not specifically relevant to this tolerance action but were submitted in response to EPA's proposed decision under FIFRA on the pending associated application for registration of a product containing 2,4-D. Because of the overlap in some of the comments, EPA has prepared a single response to comments document, which can be found in this docket, which is also the same docket for the pending pesticide action.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a

reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 2,4-D, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with 2,4-D follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The toxicity profile shows that 2,4-D is not acutely toxic via the oral, dermal, and inhalation routes, is not a dermal irritant or a dermal sensitizer, but it is a severe eye irritant. The principal toxic effects are changes in the kidney [increased kidney weight, histopathological lesions], thyroid [decreased thyroxine, increased thyroid weight, hyperplasia and hypertrophy of follicular cells], liver [increased liver weight, increased ALT and AST, histopathological lesions, including hypertrophy], adrenal [increased adrenal weight, histopathological lesions], eye [retinal degeneration, cataract formation, lens opacity], and ovaries/testes [decreased testes weight and ovarian weight, atrophy] in the rat following exposure to 2,4-D via the oral route at dose levels above the threshold of

saturation of renal clearance. No systemic toxicity was observed in rabbits following repeated exposure via the dermal route at dose levels up to the limit dose. Neurotoxicity, as evidenced by the increased incidence of incoordination and slight gait abnormalities (forepaw flexing or knuckling) was observed in the acute neurotoxicity study in rats at the highest dose. In an extended 1-generation reproductive toxicity study in rats, reproductive toxicity, developmental neurotoxicity, and immunotoxicity were not observed, and the thyroid effects observed at dose levels up to/approaching renal saturation were considered treatment-related, although not adverse. Neuropathological effects were not observed in any study. Maternal and developmental toxicity were observed at high dose levels exceeding the threshold of saturation of renal clearance. There are no residual uncertainties for pre- and/or postnatal toxicity. 2,4-D has been classified as a Category D chemical, “not classifiable as to human carcinogenicity”, based upon bioassays in rats and mice that showed no statistically significant tumor response in either species. The Agency has determined, based on several reviews of epidemiological studies, in addition to the animal studies, that the existing data do not support a conclusion that links human cancer to 2,4-D exposure. Specific information on the studies received and the nature of the adverse effects caused by 2,4-D as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document, **2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Cotton** at pgs. 40-50 in docket ID number EPA-HQ-OPP-2016-0594.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for 2,4-D used for human risk assessment is shown in Table 1 of this unit.

Table 1.-Summary of Toxicological Doses and Endpoints for 2,4-D for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary	Developmental	Acute RfD =	Developmental Toxicity

(Females 13-50 years of age)	NOAEL = 25 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	0.25 mg/kg/day $aPAD = .025$ mg/kg/day	Study – rat Developmental LOAEL = 75 mg/kg/day based on fetal skeletal abnormalities (14 th rudimentary ribs)
Acute dietary (General population including infants and children)	NOAEL = 67 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = 0.67 mg/kg/day $aPAD = 0.67$ mg/kg/day	Acute Neurotoxicity Study – rat LOAEL = 227 mg/kg/day based on slight gait abnormalities (forepaw flexing and knuckling) and increased incidence of incoordination
Chronic dietary (All populations)	NOAEL = 21 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.21 mg/kg/day $cPAD = 0.21$ mg/kg/day	Extended 1-generation Reproduction- rat Parental LOAEL = 55.6 mg/kg/day (males) and 46.7 mg/kg/day (females) based on kidney toxicity manifested as increased kidney weights and increased incidence of degeneration of the proximal convoluted tubules and for offspring based on decreased body weight observed throughout lactation.

<p>Incidental oral short- and intermediate term</p> <p>(1 to 30 days and 1-6 months)</p>	<p>NOAEL= 21 mg/kg/day</p> <p>UF_A = 10x</p> <p>UF_H = 10x</p> <p>FQPA SF = 1x</p>	<p>LOC for MOE = 100</p>	<p>Extended 1-generation Reproduction- rat</p> <p>Parental LOAEL = 55.6 mg/kg/day (males) and 46.7 mg/kg/day (females) based on kidney toxicity manifested as increased kidney weights and increased incidence of degeneration of the proximal convoluted tubules and for offspring based on decreased body weight observed throughout lactation.</p>
<p>Dermal (all durations)</p>	<p>No potential hazard <i>via</i> the dermal route, based on the lack of systemic effects following repeat dermal exposure of rabbits at dose levels up to 1000 mg/kg/day. Although developmental toxicity was not assessed in the dermal study, clear NOAELs (dermal equivalent doses of 250 and 300 mg/kg/day) were determined; the developmental effects occurred at dose levels that exceed renal clearance mechanism (dermal equivalent doses of 750 and 900 mg/kg/day); dose levels required to exceed the renal clearance mechanism would not be attained following dermal exposure to humans.</p>		
<p>Inhalation (all durations)</p>	<p>Inhalation study</p> <p>LOAEL= 0.05 mg/L/day</p> <p>HEC = 0.013 mg/L/day (bystander)</p> <p>HED = 1.76 mg/kg/day</p>	<p>LOC for MOE = 300</p>	<p>Subchronic inhalation toxicity study- rat</p> <p>LOAEL = 0.05 mg/L/day based on portal-of-entry effects (squamous metaplasia and epithelial hyperplasia with increased mixed inflammatory cells within the larynx); not totally resolved following a 4-week recovery period</p>

	(residential handler)		
	$UF_A = 3x$ $UF_H = 10x$ $UF_L = 10x$		
Cancer (Oral, dermal, inhalation)	Classification: Group D – not classifiable as to human carcinogenicity		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. HEC = Human Equivalent Concentration (mg/L). HED = Human Equivalent Dose (mg/kg/day).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 2,4-D, EPA considered exposure under the petitioned-for tolerances as well as all existing 2,4-D tolerances in 40 CFR 180.142. EPA assessed dietary exposures from 2,4-D in food as follows:

i. *Acute and chronic exposure.* In estimating acute and chronic dietary exposure, EPA used 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed that 100% of all crops had been treated and conservative default processing factors were used for all relevant processed commodities. EPA also assumed tolerance-level residues for all commodities

excluding transgenic soybean and cotton commodities. For transgenic soybean, the combined 2,4-D and 2,4-DCP residues were used for the acute and chronic dietary analyses as the combined residues found in tolerant soybean were greater than the tolerance of parent only for soybean. Since residue levels of parent 2,4-D in/on tolerant soybean were non-detectable, estimated 2,4-D residues (at ½ the level of detection of 0.003 ppm, or 0.0015 ppm) were added to the 2,4-DCP highest average field trial residue (HAFT is 0.047 ppm) to be used in the acute and chronic dietary analyses. For the proposed new use on transgenic cotton, a combined 2,4-D and 2,4-DCP residue value of 0.15 ppm was used in the acute and chronic dietary assessment for cotton seed oil. For 2,4-D, it was not possible to calculate a processing factor for refined oil because residues were non-detectable in both the RAC and the oil in the processing study. Therefore, the Agency used a processing factor of 1.0x, multiplied by the HAFT of undelinted cotton seed (0.07 ppm) from the recently submitted magnitude of residue study. The 2,4-DCP processed commodity residue for refined oil (0.08 ppm), was calculated by multiplying the processing factor of 0.4x by the HAFT of undelinted cotton seed for 2,4-DCP (0.206 ppm). The 2,4-D residue product (0.07 ppm) was then added with the 2,4-DCP residue product (0.08 ppm) and the sum was 0.15 ppm.

ii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that 2,4-D does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iii. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for 2,4-D. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 2,4-D in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of 2,4-D. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Modeled estimates of drinking water concentrations based on the Surface Water Concentration Calculator (SWCC) were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 298 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 34.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

2,4-D is currently registered for the following uses that could result in residential exposures: ornamental turf, including parks, sports fields, and golf courses, as well as aquatic uses. The existing residential uses were previously assessed in 2013. However, since that time there have been changes to the policy for calculating inhalation HECs and the policy for assessing aquatic exposure; therefore, the residential scenarios have been reassessed. EPA assumes that residential handlers complete all elements of an application without use of any protective equipment or baseline attire such as long pants

and long-sleeved shirt. Quantitative short-term inhalation exposure estimates for adult residential handlers are based on the scenarios of mixing, loading, and application of 2,4-D to lawns and turf at maximum rates using hose-end sprayers, manually-pressurized hand wands, and backpack sprayers with liquid and ready-to-use forms, as well as belly grinders and push-type spreaders. Intermediate-term exposures are not likely and were not estimated because of the intermittent nature of applications by homeowners. Dermal exposures were also not estimated due to the lack of dermal hazard.

In addition to residential handler exposure, the following post-application exposure scenarios were estimated for short-term duration to protect adults and children that might be playing in treated turf areas or swimming in treated aquatic areas after applications of 2,4-D have been made at the maximum rates:

- Incidental ingestion (i.e., hand-to-mouth, object-to-mouth, soil ingestion exposure) from contact with treated turf (children 1 < 2 years old only)
- Episodic granular ingestion on treated turf (children 1 < 2 years old only)
- Incidental ingestion of water during recreational swimming (both adults and children 3 < 6 years old).

None of the above exposure scenarios resulted in handler or post-application risk estimates that exceed EPA's level of concern. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found 2,4-D to share a common mechanism of toxicity with any other substances, and 2,4-D does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2,4-D does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is evidence of increased susceptibility following *in utero* exposure to 2,4-D in the rat developmental toxicity study and following *in utero* and/or pre-/post-natal exposure in the rat 2-generation reproduction study. There is no evidence of increased susceptibility following *in utero* exposure to 2,4-D in the rabbit developmental toxicity study or following *in utero* and/or pre-/post-natal exposure in the rat extended 1-generation reproduction toxicity study.

2,4-D has been evaluated for potential developmental effects in the rat and rabbit.

Maternal toxicity included decreased body weight gains in the rat study at the same dose level where developmental effects (occurrence of skeletal malformations) were observed. Kidney effects would have been expected in the maternal animal had examination of the kidney been performed, and the findings are not considered evidence of susceptibility.

Maternal toxicity in the rabbit included decreased body weight gain, clinical signs of toxicity (decreased motor activity, ataxia, loss of righting reflex, extremities cold to the touch), and abortions, the latter being indicative of developmental toxicity. Decreased maternal body weight gains were observed in the rat 2-generation reproduction study at a dose that exceeded renal saturation and resulted in reduced viability of the F1 pups.

Although decreased maternal body weight gain is a conservative endpoint, points of departure used in the risk assessment are below where these findings occur and are protective. There are clearly established NOAELs and LOAELs for the population of concern, there are no data gaps in the toxicology database, and the points of departure (POD) are protective of susceptibility. The exposure assessment will not underestimate children's exposure to 2,4-D.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for 2,4-D is complete.
- ii. Although there are indications of neurotoxicity observed in the acute neurotoxicity study in rats, as evidenced by an increase in the incidence of incoordination and slight gait abnormalities (forepaw flexing or knuckling) at the high dose in both sexes, developmental neurotoxicity was not observed in the developmental neurotoxicity segment of the extended 1-generation reproductive toxicity study in rats.
- iii. For the reasons stated in Unit III.D.2., there is no residual uncertainty concerning the potential susceptibility of infants and children to effects of 2,4-D; therefore, there is no need to retain the 10X FQPA safety factor to protect infants and children.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated and tolerance-level or higher residues assumptions. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 2,4-D in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by 2,4-D.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to 2,4-D will occupy 23% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 2,4-D from food and water will utilize 20% of the cPAD for children 1 to 2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of 2,4-D is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). 2,4-D is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to 2,4-D. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result

in aggregate MOEs of 2,000 for adults, 560 for children ages 3-5 that are exposed to 2,4-D residues via incidental ingestion of treated water during swimming activities. The aggregate MOE of 280 is estimated for children ages 1-2 that exhibit hand-to-mouth behavior on treated turf. Because EPA's level of concern for 2,4-D is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, 2,4-D is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for 2,4-D.

5. *Aggregate cancer risk for U.S. population.* Based on bioassays in rats and mice that show no statistically significant tumor response in either species as well as several reviews of epidemiological studies, in addition to the animal studies, the Agency has classified 2,4-D as a Category D chemical, *i.e.*, not classifiable as to human carcinogenicity, and is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 2,4-D residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods are available for data collection and the enforcement of plant commodity tolerances, including cotton. Task Force II submitted an adequate GC/ECD enforcement method for plants (designated as EN-CAS Method No. ENC-2/93) which has been independently validated and radiovalidated. An enforcement method was submitted for determination of 2,4-D in livestock commodities, which has been adequately radiovalidated. The methods have been submitted to FDA for inclusion in PAM II. The 10/1997 edition of FDA PAM Volume I, Appendix I indicates that 2,4-D is partially recovered (50-80%) using Multiresidue Methods Section 402 E1 and 402 E2.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA

section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for 2,4-D on cotton.

V. Conclusion

Therefore, tolerances are established for residues of 2,4-D (2,4-dichlorophenoxyacetic acid) in or on gin byproducts and undelinted seed of cotton at 1.5 and 0.08 ppm respectively.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act

(PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 9, 2017,

Michael J. Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.142:

- a. Add alphabetically the commodities “Cotton, gin byproducts” and “cotton, undelinted seed” to the table in paragraph (a); and
- b. Remove the entry for “cotton, undelinted seed” from the table in paragraph (d) to read as follows:

§ 180.142 2,4-D; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * *	* * *
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.08
* * * *	* * *

* * * * *

[FR Doc. 2017-02477 Filed: 2/6/2017 8:45 am; Publication Date: 2/7/2017]